

### **REMARKS/ARGUMENTS**

At the outset, Applicants thank the Office for acknowledging the allowable subject matter of claims 3, 15, and 16.

Independent claims 1, 2, and 5 have been amended to recite that the size of the amplified hsp 65 gene fragment is 604 bp excluding the primers. Independent claim 4 has been amended to recite that the set consists of at least two hsp gene fragments. Independent claim 5 has also been amended by replacing the word “analyzing” with “sequencing” and by removing the phrases “a polynucleotide set which consists of” and “to infer a phylogenetic tree”. Independent claim 8 has been amended to recite that the size of the amplified hsp 65 gene fragment is 644 bp including the primers. Support for each of these amendments can be found throughout the application as originally filed, including paragraphs [0018]-[0020], [0039], [0057]-[0063] of the published application (i.e., U.S. 2005/0014157). Accordingly, no new matter has been entered.

#### **Claim Rejections Under 35 U.S.C. §112**

##### **A.**

Claims 1, 2, 5, and 8-14 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Office argues that it is unclear as to the size of the fragment. Applicants respectfully traverse this rejection.

As described throughout the present specification, Applicants note that the size of the hsp 65 gene fragment is 604 bp when excluding the primers and 644 bp when including the primers. To clarify this point, independent claims 1, 2, and 5 have each been amended to expressly recite that the size of the amplified hsp 65 gene fragment is 604 bp excluding the primers. Similarly, independent claim 8 has been amended to expressly recite that the size of the amplified hsp 65 gene fragment is 644 bp including the primers. As currently amended, each independent claims clearly recites the specific size of the amplified hsp 65 gene fragment. Accordingly, Applicants submit that this indefinite rejection has been overcome and request that this rejection be withdrawn.



**B.**

Claim 2 stands rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Office argues that claim 2 is indefinite because the claim is directed to “a polynucleotide of an hsp 65 gene fragment”, which the Office interprets as encompassing a sequence of 2 or 3 nucleotides. Applicants respectfully traverse this rejection.

As discussed throughout the present specification, the recited primer set (i.e., SEQ ID NO: 55 and SEQ ID NO: 56) amplifies only 604-bp hsp 65 gene fragment of mycobacterial species. Furthermore, claim 2 has been amended to expressly recite that the size of the amplified hsp 65 gene fragment is 604 bp excluding the primers. Applicants submit that the current amendment clarifies the rejected wording of “a polynucleotide of an hsp 65 gene fragment”. Accordingly, Applicants submit that this rejection has been overcome and request withdrawal thereof.

**C.**

Claim 4 stands rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Office argues that it is unclear how one has a “set” if only one sequence is chosen. Applicants respectfully traverse this rejection.

For the purpose of clarification only, claim 4 has been amended to recite that the set consists of at least two hsp 65 gene fragments selected from the group of polynucleotides consisting of SEQ ID NO: 1 to SEQ ID NO: 54 and polynucleotides complementary thereto. Applicants submit that the amendment to claim 4 overcomes the indefinite rejection and request withdrawal thereof.

**D.**

Claim 5 stands rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Office argues that it is unclear what steps are involved in “analyzing” a nucleotide sequence, how one has a “set” if only one sequence is chosen, and what is meant by “infer a phylogenetic tree”.



With regard to the term “analyzing”, claim 5 has been amended by replacing this term with “sequencing”. The use of the term “sequencing” is supported at least by the Examples of the present specification. Applicants note that one skilled in the art would readily understand and recognize what is meant by the term “sequencing” due at least to the common use of this term in the relevant art. Additionally, the Applicants note that the Examples of the present specification also facilitate the understanding of the meaning of the term “sequencing” as recited in the currently amended claims. Applicants submit that this amendment overcomes this basis for rejecting claim 5 as being indefinite.

With regard to the ambiguity associated with the term “set” and “one hsp 65 gene fragment”, claim 5 has been amended by deleting the phrase “a polynucleotide set which consists of”. Applicants submit that this amendment overcomes this basis for rejecting claim 5 as being indefinite.

Regarding the phrase “to infer a phylogenetic tree”, Applicants have deleted this phrase. Applicants submit that this amendment overcomes this basis for rejecting claim 5 as being indefinite.

Applicants respectfully submit that independent claim 5, as currently amended, satisfies all requirements under 35 U.S.C. §112 and request withdrawal of this rejection.

### **Conclusion**

In view of at least remarks made above, Applicants submit that the pending claims are in condition for allowance. Applicants respectfully request that the claims be allowed to issue. **If the Examiner wishes to discuss the application or the comments herein regarding the current rejections under 35 U.S.C. §112 or additional concerns related to 35 U.S.C. §112, the Examiner is urged to contact the undersigned.**

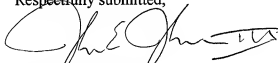
It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required



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therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "John E. Johnson, III", written over the typed name.

John E. Johnson, III  
Registration No. 58,367

Customer No. 00826  
**ALSTON & BIRD LLP**  
Bank of America Plaza  
101 South Tryon Street, Suite 4000  
Charlotte, NC 28280-4000  
Tel Charlotte Office (704) 444-1000  
Fax Charlotte Office (704) 444-1111  
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